UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,345	03/12/2004	Christopher T. Ritchlin	21108.0031U2	6683

23859 7590 09/11/2007

NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,345	RITCHLIN ET AL.	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Upon further consideration, claims 1-93 are subjected to restriction requirement as follows:

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31, 33-45, and 49, drawn to method of diagnosing a subject with inflammatory joint disease (IJD) by measuring osteoclast precursor cells (OCP) and kit therefor, classified in class 436, subclass 811, for example.

II. Claim 32, drawn to method of diagnosing IJD by culturing peripheral blood mononuclear cells and measuring concentration of TNF-α protein that is secreted, classified in class 435, subclass 374, for example.

III. Claims 46-48, drawn to method of diagnosing IJD by culturing peripheral blood mononuclear cells on cortical bone wafers and measuring the amount of eroded bone, classified in class 435, subclass 1.1, for example.

IV. Claims 50-71 and 80-93, drawn to method of treatment and monitoring treatment of IJD, classified in class 424, subclass 9.2, for example.

V. Claims 72-74, drawn to method of identifying an agent having the ability to treat IJD, classified in class 436, subclass 517, for example.

VI. Claims 75-79, drawn to a kit, classified in class 422, subclass 61, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are independent and distinct methods and kit. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions different designs, modes of operation, different functions, and different effects in that Invention I obtains a measure of any one of the osteoclast precursors after culturing peripheral blood mononuclear cells and determines a concentration that is diagnostic of IJD; Invention II obtains a measure of TNF-α protein that is secreted after culturing peripheral blood mononuclear cells and determines a concentration that is diagnostic of IJD; Invention III provides indication of IJD by culturing peripheral blood mononuclear cells on cortical bone wafers and measuring the amount of eroded bone; Invention IV obtains different measures of OCP at different time frames to determine an improvement of IJD by virtue of improved measured concentrations of OCP; and Invention V determines if a pharmaceutical agent has the ability to treat IJD by administering the test agent to a patient subject and then monitoring an improvement of the concentrations of OCD, wherein a decrease in the amount of OCD provides a determination that the test agent has a pharmaceutical efficacy to treat IJD, and Invention VI is a kit.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because the search

required for each one of Groups I-VI is not required for the other of each of Groups I-VI, restriction for examination purposes as indicated is proper. Literature search for each method and kit is distinct since the structural requirements of each invention are different. While searches would be expected to overlap, there is no reason to expect the searches to be coextensive.

2. This application contains claims directed to the following Subgroups of patentably distinct species:

A) Markers - recited in claims 3-10, 13, 14, 23, 36, 49, 70, 74, 75, and 79:

CD14, CD11a, CD11b, CD51/CD61, RANK, CCR1, CCR4, VCAM (CD106), VLA-4 (CD49d), CD16, MHC Class II, B7.1, B7.2, CD40, and c-fms.

B) Selected number of markers - recited in claims 3-10, 14, 23, and 38-44, :

At least one, at least two, at least three, at least four, at least five, at least six, at least seven, and at least eight.

C) Samples – recited in claims 16-18:

Blood, synovium, bone marrow.

D) Methods of measurement - recited in claims 13-15, 19-21, 27, 34, and 37.

FACS, TRAP, colorimetric assay, Immunohistrochemistry, Western Blot, Southern methods, Hybridization methods, RT-PCR methods,

ELISA, ELISPOT, Microarray, Bone marrow resorption methods, Immunoprecipitation.

E) Anti-inflammatory disease agents - recited in claims 54-69, 82, and 83.

OPG, infliximab, etanercept, adludimab, kinaret, raptiva, osteoprotegerin (OPG), RANKFc, anti-RANKL, Biphosphonate-pamidronate, alendronate, azulfidine, hydroxychloroquin, corticosteroid-prednisone, methylprednisone, TNF-R2.

F) Administration time frame - recited in claims 85-90.

At least one month, at least two months, at least three month, at least four months, at least five month, at least six months.

The species in each one of SubGroups A) to F) are independent or distinct because the species from each one of subgroups A) to F) all have different structural and functional requirements. Applicant is required to select a species from each one of subgroup A) to F).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 2, 11, 12, 22, 24-26, 28-33, 35, 38-53, 71-73, 76-81, 84, and 91-93 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Primary Examiner
Art Unit 1641

September 4, 2007